

Applicants : Lorna W. Role et al.
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Applicants respectfully request that, in view of the remarks made herein, the Examiner withdraw the outstanding rejections.

Formalities

The Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures, attached hereto as **Exhibit A**, requires that applicants submit a paper copy and computer readable form of a Sequence Listing, along with a Statement under 37 C.F.R. §1.821(f). Accordingly, applicants hereby submit a Sequence Listing, attached hereto as **Exhibit B**, in compliance with the requirements of §1.821-1.825. In addition, applicants submit herewith the Sequence Listing on the enclosed computer diskette. Applicants also submit as **Exhibit C** a Statement In Accordance With 37 C.F.R. §1.821(f) certifying that the contents of the computer readable form and paper copy are the same, and raise no issue of new matter.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 30-34 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner asserts that the skilled artisan cannot make or use the broad genus of "nARIA polypeptide."

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In response, applicants respectfully traverse the rejection.

Briefly, claims 30-34 provide a method for determining whether an agent is capable of modulating the binding of a nARIA polypeptide to a receptor selected from the group consisting of erbB2, erbB3 and erbB4.

Applicants maintain that a representative number of nARIA polypeptides have been set forth in the subject application to enable the instant method. For example, both human and chicken nARIA polypeptides are disclosed at, *inter alia*, page 10 of the specification. Applicants note that disclosure of all possible nARIA polypeptides is not required for establishing enablement, or written description for that matter. Rather all that need be provided is a representative number of such polypeptides.

In addition, at *inter alia*, pages 21-26 of the specification, applicants have described in sufficient detail the structure of nARIA polypeptides and identified specific modifications to human and chicken nARIA polypeptides as encompassed in the claims. Based on such disclosures, one skilled in the art could, without undue experimentation, make other nARIA polypeptides. For the above reasons, applicants maintain that claims 30-34 are enabled.

The Examiner also rejected claims 30-34 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession

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of the claimed invention.

In response, applicants respectfully traverse the rejection. Applicants' traversal is based on the reasons set forth above in connection with the Examiner's enablement rejection.

In view of the above remarks, applicants maintain that claims 30-34 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 30-34 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In response, applicants respectfully traverse the rejection.

In support of the rejection, the Examiner asserts that the phrase "the agent" in claim 20 is vague and unclear.

In response, applicants point out that claim 20 was canceled, without prejudice, in applicants' August 27, 2002 Amendment. Since the Examiner's rejection appears to be solely based on previously canceled claim 20, applicants submit that the rejection of claims 30-34 should be withdrawn. In addition, applicants note that pending claim 30 clearly sets forth how "the agent" is supposed to be used. Claim 30 recites, in relevant part, "(a) contacting the nARIA polypeptide with the

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agent" and "(c) comparing the amount so measured in step (b) to the amount of the nARIA polypeptide which binds to the receptor in the *absence of the agent*" (emphasis added). It is also noted that further information concerning the nature of the agent is unnecessary in the context of the pending claims.

In view of the above remarks, applicants maintain that claims 30-34 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. §102(b)

The Examiner rejected claims 30-33 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,602,096 to Goodearl ("Goodearl").

In response, applicants respectfully traverse the rejection.

Again, the claimed invention provides methods for determining whether an agent is capable of modulating the binding of a *nARIA polypeptide* to a receptor selected from the group consisting of erbB2, erbB3 and erbB4. Contrary to the Examiner's position, this method requires, in relevant part, contacting the nARIA polypeptide with the receptor in the presence of the agent. For a reference to anticipate the instant invention, it would have to teach *all the elements thereof*.

Clearly, Goodearl fails to do this, and the Examiner has not shown otherwise. According to the Examiner, Goodearl teaches glial growth factors (GGF) that "possess nARIA activity" and

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competitive assays with GGF and antibodies. Goodearl fails to teach a *nARIA polypeptide* or any assay involving a *nARIA polypeptide*. It is irrelevant that, according to the Examiner, GGF posses nARIA activity. Claims 30-33 do not recite GGF but instead recite nARIA polypeptide. The Examiner has not provided any teaching that suggests that GGF is the same as nARIA polypeptide. Applicants maintain that Goodearl fails to anticipate the instant invention, because it does not teach each and every element of the claimed method.

Finally, applicants note the Examiner's assertion that the claims as presently written do not require the presence of an agent. Applicants disagree with the Examiner and point out that the rejected claims provide for, in relevant part, contacting the nARIA polypeptide with an agent. Applicants direct the Examiner's attention to step (a) of claim 30 for an example of this language.

In view of the above remarks, applicants maintain that claims 30-33 satisfy the requirements of 35 U.S.C. §102(b).

Rejection Under 35 U.S.C. §102(e)

The Examiner rejected claims 30-34 under 35 U.S.C. §102(e) as allegedly anticipated by U.S. Patent No. 6,284,535 B1 ("Role").

In response, applicants respectfully traverse the rejection.

Claims 30-34 are discussed above, as is the standard for anticipation.

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As with Goodearl, Role fails to teach each and every element of the claimed method. Specifically, as applicants noted in their August 27, 2002 Amendment, nowhere does Role disclose "contacting the nARIA polypeptide to a receptor selected from the group consisting of erbB2, erbB3 and erbB4, under conditions permitting the binding of the nARIA polypeptide to the receptor in the absence of the agent." The Examiner has not responded to the arguments set forth in applicants' August 27, 2002 Amendment, indicating how Role anticipates the instant invention by providing the above-described disclosure.

Finally, applicants again note the Examiner's assertion that the claims as presently written do not require the presence of an agent. Applicants disagree with this assertion for the reason set forth above.

In view of the above remarks, applicants maintain that claims 30-34 satisfy the requirements of 35 U.S.C. §102(e).

Rejection Under 35 U.S.C. §102(f)

The Examiner rejected claims 30-34 under 35 U.S.C. §102(f) as allegedly derived from U.S. Patent No. 6,284,535 B1.

In response, applicants respectfully traverse the rejection.

New claims 30-34 are discussed above.

In response to the Examiner's rejection, applicants again point

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out that nowhere does Role recite "contacting the nARIA polypeptide with the agent and a receptor selected from the group consisting of erbB2, erbB3 and erbB4, under conditions permitting the binding of the nARIA polypeptide to the receptor in the absence of the agent." Rather, this subject matter and the claimed method comprising it, disclosed only in the instant application, are the invention of the three named applicants. Thus, the Examiner's assertion of derivation is without merit.

Applicants maintain that, for the reasons stated above, claims 30-34 satisfy the requirements of 35 U.S.C. §102(f).

Rejection Under 35 U.S.C. §103(a)

The Examiner rejected claims 30-34 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 5,602,096 to Goodearl et al. ("Goodearl") in view of U.S. Patent No. 6,284,535 B1. Applicants' acknowledge the Examiner's comments regarding the August 27, 2002 Amendment.

In response, applicants respectfully traverse the rejection. Applicants maintain that the Examiner has failed to establish a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim. First, the cited references, when combined, teach or suggest every element of the claim. Second, one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention. And third, there would

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have been a reasonable expectation that the claimed invention would succeed.

Applicants maintain that the cited references fail to support a *prima facie* case of obviousness of claims 30-34.

The rejected claims provide methods for determining whether an agent is capable of modulating the binding of a nARIA polypeptide to a receptor selected from erbB2, erbB3 and erbB4. The cited references are discussed above.

Applicants maintain that the cited references, when combined, do not teach or suggest every element of the claims. Specifically, nowhere does either reference teach the binding of a nARIA polypeptide to an erbB2, erbB3 and erbB4 receptor in the presence of an agent. The Examiner alleges that such teachings are made by the references, but has not specifically cited where such teachings are made. Given that Goodearl and Role combined do not teach all the elements of claims 30-34, it follows that these references also fail to create a motive to combine or a reasonable expectation of success.

In view of the above remarks, applicants maintain that the Examiner has failed to set forth a *prima facie* case of obviousness, and that accordingly, claims 30-34 satisfy the requirements of 35 U.S.C. §103(a).

Conclusion

Applicants maintain that claims 30-34 are in condition for

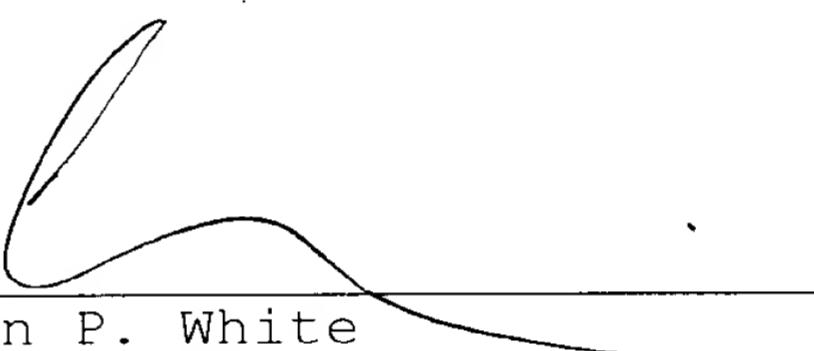
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allowance, and thus, allowance is respectfully requested.

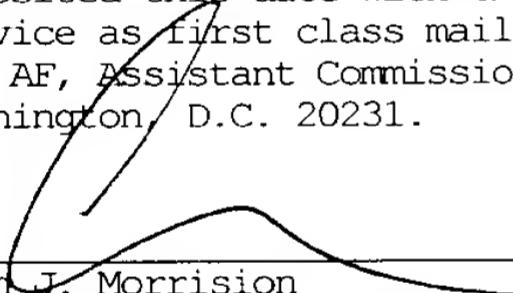
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

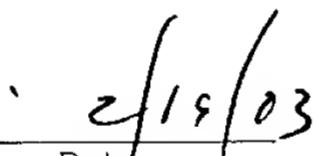
No fee is deemed necessary, in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,


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I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to:
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